ABSTRACT OF THE DISCLOSURE

The present invention relates to a method and system for planning a stability study of a pharmaceutical composition. According to the current invention a new statistical principle for designing studies is provided. It addresses directly that the aim of the stability study is to derive more precise and efficient specification limits. The method involves making estimates of the needs that might be encountered and in that way determine whether a given stability study model can provide the precision necessary to derive appropriate shelf-life specifications. The approach is based on utilizing normal distribution calculations of the obtainable specifications in Allen's formula. The terms that are estimated include the degradation rates such that in the estimated model, the specifications arrived at have at least a 90% chance of being better than projected by other methods. In addition the standard evaluation of the uncertainty of the slope is performed. Data at accelerated temperatures are other conditions may also be included to increase precision.